

# EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

## MDR 720081 R000

**Manufacturer:** STIMULI TECHNOLOGY

**Address:**

20 bis rue Barthélemy Danjou  
Boulogne Billancourt  
92100  
France

**Single Registration Number:** Not Available

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-02-02**

Date: **2021-02-02**

Expiry Date: **2026-02-01**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
TENSI+ (Neuromuscular electro stimulator)	Class IIa



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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference number	Action
Current	3095636	Initial Issue



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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.

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## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

### MDR 720081 R000

Date: 2021-02-02

Critical Subcontractor/Crucial Supplier	Service(s) supplied
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BSE Electronics 616 avenue de l'Europe BP 87 Le Creusot 71200 France	<b>Assembly</b> <b>Final Inspection</b> <b>Labelling</b> <b>Manufacture</b>
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